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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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05/11/2006

Anders Visko Nielsen

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12/06/2006

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/578,992	NIELSEN ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/11/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>SEQ ALIGN</u> . |

Detailed Action

Claims 44-54 are pending in this application and are now under consideration for examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 PCT/DK04/00406 filed on 06/11/2004 and claims the priority date of Denmark application 2003 00884 filed on 06/13/2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05/11/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Abstract

The abstract of the disclosure is objected to because the abstract should be on a separate sheet of paper. Correction is required. See MPEP § 608.01(b).

Claim Rejections 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 44 is rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claim is drawn to a 'A filamentous fungal host cell', which could read on

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product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated filamentous fungal host cell ' to show the hand of man and in order to overcome the rejection.

Claim Rejections: 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44, 47, 50-52, 54 and claims 45-49 and 52-54 dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 44 and 50 recites the phrase "...70% identical to the sequence shown in positions 19-471 of SEQ ID NO: 2..." and claims 47, 52 and 53 recites the phrase "...80% identical to the sequence shown in positions 483-579 of SEQ ID NO: 2...", the metes and bounds of the phrase is not clear and the Examiner suggests changing the phrase to "...70% sequence identity to the sequence shown in positions 19-471 of ... and ...80% sequence identity to the sequence shown in positions 483-579 ... " respectively.

Claims 48, 52 and 54 recites the limitation "the polypeptide comprises a linker between the starch-binding domain... " in the claims. There is insufficient antecedent basis for this limitation "starch-binding domain" in the claims.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 46 and 51 are directed to a filamentous fungal host comprising a polypeptide having 70% sequence identity to region spanning amino acid residues 19-471 of SEQ ID NO: 2 having glucoamylase activity and a starch binding domain. Claims 46 and 51 are rejected under this section 35 U.S.C. 112, because the claims are directed to a genus of polypeptides with no support in the specification for the structural details associated with the function i.e., a starch binding domain of a polypeptide having 70-99% sequence identity to region spanning amino acid residues 19-471 of SEQ ID NO: 2 and having glucoamylase activity. No description of identifying characteristics of all of the starch binding domain sequences of an isolated polypeptide comprising an amino acid sequence having 78%-99% sequence identity to region spanning amino acid residues 19-471 of SEQ ID NO: 2 and having glucoamylase activity has been provided by the applicants in the specification. No information, beyond the characterization of the region spanning amino acid residues 19-471 of SEQ ID NO: 2 and having glucoamylase activity wherein said starch binding domain comprises the amino acid residues 483-579 of SEQ ID NO: 2 has been provided by the applicants, which would indicate that they had possession of the claimed genus of the polypeptides i.e., all of the starch binding domain sequences of an

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isolated polypeptide comprising an amino acid sequence having 78%-99% sequence identity to region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 44-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a filamentous fungal host comprising a polypeptide of SEQ ID NO: 2 or a region spanning the amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 with having glucoamylase activity, said polypeptide comprising a starch binding domain of amino acid residues 483-579 of SEQ ID NO: 2 or a polynucleotide with SEQ ID NO: 1 encoding for corresponding polypeptide, vector, isolated host cell and method of making said polypeptide and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptide, does not reasonably provide enablement for any filamentous fungal host comprising any polypeptide having 70%-99% sequence identity to a region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity, said polypeptide further comprising a starch binding domain spanning the amino residues 483-579 of SEQ ID NO: 2, vector, host cell comprising said polynucleotides, method of making corresponding polypeptides and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptides. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*. (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 44-54 are so broad as to encompass any filamentous fungal host comprising any polypeptide having 70%-99% sequence identity to a region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity, said polypeptide further comprising a starch binding domain spanning the amino residues 483-579 of SEQ ID NO: 2, vector, host cell comprising said polynucleotides, method of making corresponding polypeptides and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptides. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in

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which the encoded proteins' structure relates to its function. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the making and using a polypeptide of SEQ ID NO: 2 or a region spanning the amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 having glucoamylase activity, said polypeptide comprising a starch binding domain of amino acid residues 483-579 of SEQ ID NO: 2 and a polynucleotide with SEQ ID NO: 1 encoding for corresponding polypeptide in a filamentous fungal host cell, vector, isolated host cell and method of making said polypeptide and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptide, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to

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modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass all modifications and any filamentous fungal host comprising any polypeptide having 70%-99% sequence identity to a region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity, said polypeptide further comprising a starch binding domain spanning the amino residues 483-579 of SEQ ID NO: 2, vector, host cell comprising said polynucleotides, method of making corresponding polypeptides and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptides, because the specification does not establish: (A) regions of the polynucleotide/ protein structure which may be modified without affecting the activity of glucoamylase activity or the starch binding domain; (B) the general tolerance of the glucoamylase activity or the starch binding domain to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue in the polypeptide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides with an enormous number of modifications to the polypeptide of SEQ ID NO: 2 and encoding polynucleotide of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having

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the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagasaka et al., (Appl Microbiol Biotechnol., 1995, Vol. 44: 451-458). Claims 44-54 are directed to any filamentous fungal host comprising any polypeptide having 70%-99% sequence identity to a region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity, said polypeptide further comprising a starch binding domain spanning the amino residues 483-579 of SEQ ID NO: 2, vector, host cell comprising said polynucleotides, method of making corresponding polypeptides and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptides. Nagasaka et al., (*supra*) teach the isolation of a polypeptide (Q12596_9APHY) that has 99.7% homology to SEQ ID NO: 2 and 99.7% homology to a region spanning amino acid residues 19-471 or 19-579 of SEQ ID NO: 2 and having glucoamylase activity and 100% homology to the starch binding domain spanning the amino residues 483-579 of SEQ ID NO: 2 of the instant application (see sequence alignment provided) from a filamentous fungal host cell. Said reference also teaches vector, host

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cell comprising polynucleotide encoding said polypeptide, method of making corresponding polypeptide and the method of saccharifying liquefied starch comprising the treatment of liquefied starch with said polypeptide. Therefore, Nagasaka et al., anticipate claims 44-54 as written.

Conclusion


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

Nov. 02, 2006.


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